UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,606	12/12/2003	Helen M. Moore	9692-000030	2491

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EXAMINER
AGRAWAL, RITESH

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

		Application No.	Applicant(s)
		10/735,606	MOORE ET AL.
Office Action Summary		Examiner	Art Unit	
		Ritesh Agrawal	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>31 July 2006</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
      closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-35</u> is/are pending in the application.

    4a) Of the above claim(s) <u>22-35</u> is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-21</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>12 December 2003</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
      application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date <u>03/30/05, 01/31/06</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____ .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of invention I (claims 1-21) in the reply filed on 07/31/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 22-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in the reply filed on 07/31/06.

Information Disclosure Statement

The Information Disclosure Statements filed 03/31/05 and 01/31/06 have been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The alterations to the address of inventor Fu Lu were not initialed and dated.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Such code can be found, for example, on page 15 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademark MICROSOFT WINDOWS has been noted in this application, on page 38 of the specification. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-18 recite the limitation "said viewer" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 13, from which they depend, recites multiple different viewers. It is unclear to which of the multiple different viewers the limitation refers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 12-17, 19 and 21 are rejected under 35 U.S.C. 102(a) as being

anticipated by Kent et al. (Genome Research, vol. 12, pages 996-1006, June, 2002).

Claim 1 is drawn to an interactive display system encompassing a comparative

genomic database from at least two sequences and a viewer adapted to integrate the

comparative genomic data.

Kent et al. disclose, "a mature web tool for the rapid and reliable display of any

requested portion of the genome at any scale, together with several dozen aligned

annotation tracks, " (abstract, lines 2-3), thereby provided an integrated viewer system.

Furthermore, Kent et al. disclose, "the browser has a number of tracks that show

homology with other species, " (page 1000, 2nd column, 2nd paragraph, lines 1-2),

thereby providing a system with comparative genomic data of at least two species. It is

clear that the display system is interactive in that there are a number of different

controls for the user, for example, "on top is a series of controls for searching and

zooming and scrolling across a chromosome, " (page 997, 2nd column, 1st paragraph, lines 9-11).

With respect to dependent claim 2, drawn to the additional limitation of an ortholog identifier, Kent et al. disclose that, "you can also enter the browser via a search for homologous regions to a DNA or protein sequence using the "BLAT" link, " (page 997, 2nd column, 1st paragraph, lines 5-7). Thus BLAT allows one to find orthologous sequences.

With respect to claim 3 with the additional limitation of syntenic anchors, the browser system of Kent et al. includes a synteny track for syntenic regions between mouse and human sequences (see, for example, figure 1).

With respect to claim 4 requiring the presence of mouse and human comparative genomic data, Kent et al. disclose the presence of such data, for example, as cited for claim 3.

With respect to claims 5 and 6, the web system of Kent et al. had integrated information on rat sequences in November of 2002 (see page 1 of 3 of the attached printout on browser archive history, printed from the website at <http://genome-archive.cse.ucsc.edu> on 08/08/06).

With respect to claim 7, requiring the inclusion of markers with the comparative genomic data, Kent et al. disclose, for example, the mapping of STS markers in relation to chromosomal sequence (see, for example, figure 4 for the mapping of STS sites with chromosomal sequence and aligned mouse (mouse BLAT) sequences).

With respect to claim 8, requiring assembly contigs and fragments from which they're generated, Kent et al. disclose that, "the browser displays assembly contigs," (abstract, line 4), and that the browser contains a track for BAC clones from which contigs are generated (see for example figure 1).

With respect to claim 9 drawn to the additional limitation of a viewer with annotation information associated with transcribed regions, the system provides for several tracks related to the annotation of protein coding genes including Genscan predictions, Fgenesh++ prediction, Known genes, and Ensembl genes (see figure 1).

With respect to claim 10 drawn to a synteny viewer, the system of Kent et al. provides for a viewer to visualize mouse-human synteny in the mouse synteny track (see figure 1).

With respect to claim 12, drawn to the additional limitation of a viewer which displays individual nucleotides, Kent et al. disclose the ability of a user to visualize sequences on a, "base-by-base view," (page 996, 1st column, 2nd paragraph, line 5).

With respect to claims 13 and 15-17, Kent et al. disclose a system with five viewer components including a map viewer, a TA viewer, an evidence viewer, a synteny viewer, and a trace viewer and therefore meet the limitations of these referenced claims.

With respect to claim 14, drawn to the additional limitation of a viewer in which the user can select the viewer components, where Kent et al.'s tracks correspond to different viewers Kent et al. disclose, "each track can be displayed in dense mode, fully expanded, or can be hidden, " (page 997, 2nd column, 2nd paragraph, lines 4-6).

With respect to claim 19 requiring "substantially complete sequence," since the browser uses the assembled whole human genome sequence and, "whole genome shotgun reads . . . to an ~2.5 depth, " (page 1001, 1st column, 1st paragraph, lines 5-6 and 9), their coverage of the two genomic sequences should be "substantially complete."

With respect to claim 21 where the browser is provided in a web-based format, Kent et al. disclose that the browser they've developed is a web tool and provided at, " genome.ucsc.edu," (page 996, abstract, lines 2 and 4).

Claims 1, 3, 4, 8, 9, 10, 13, 15, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Semple (Genome Biology, vol. 2, pages 2001.I-2001.6, June, 2001).

Claim 1 is drawn to an interactive display system encompassing a comparative genomic database from at least two species and a viewer adapted to integrate the comparative genomic data.

Semple discloses that, "there are three well designed websites [Ensembl, UCSC Human Genome Browser, and NCBI map viewer] offering users the chance to browse annotations of the draft human genome. Essentially, all three sites offer a graphical interface to display the results of various analyses, " (page 2001.3, 1st column, 3rd paragraph, lines 1-4). It can further be inferred that Ensembl contains comparative genomic data from at least two species from its ability to display, "regions of homology [between human and] . . . mouse draft genomic sequences, " (page 2001.3, 2nd column, 1st paragraph, line 12). Furthermore, it can be inferred that the UCSC browser contains

comparative genomic data from the fact that it, "indicates regions [of the human

genome] with significant homology to the incomplete genome of the pufferfish

Tetraodon nigroviridis, " (page 2001.4, 1st column, 1st paragraph, line 5).

With respect to dependent claim 3 with the additional limitation of the

comparative genomic data including syntenic anchors, since the UCSC and Ensembl

browsers contain regions of homology they contain regions of synteny.

With respect to dependent claim 4 with the additional limitation of the two species

being mouse and human, Semple discloses the presence of comparative genomic

information from mouse and human in the Ensembl browser as disclosed above.

With respect to dependent claim 8 with the additional limitation of a viewer which

shows a contig and fragments from which it's derived, Semple discloses that

functionality in the UCSC browser, "[g]raphical representation of the fragments making

up a region of draft genome can be displayed, " (page 2001.4, 1st column, 1st

paragraph, lines 11-13).

With respect to dependent claim 9 with a viewer which displays information

associated with transcribed regions, Semple discloses that Ensembl provides for, "tRNA

gene predictions, Unigene clusters, . . . [and] disease genes, " (page 2001.3, 2nd

column, 1st paragraph, lines 8-9). Furthermore, Semple discloses that the UCSC

browser, "includes predictions from more than one *ab initio* gene-prediction program,"

(page 2001.3-2001.4, 2nd column, 2nd paragraph, line 6-line 1).

With respect to dependent claim 10 with a synteny viewer, the ability of the

UCSC and Ensembl browsers to display regions of homology provides for their ability to

display regions of synteny.

With respect to claims 13 and 15 requiring multiple viewer components, in

disclosing the details of the Ensemble system Semple discloses a viewer with two

viewer components (the synteny viewer and the evidence viewer) thus disclosing the

limitations of claim 13. In disclosing the details of the UCSC browser which contains

three viewer components (the synteny viewer, the evidence viewer, and the TA viewer)

Semple discloses the limitations of claims 13 and 15.

With respect to claim 21 with the additional limitation that the display system be

provided in web-based format, Semple discloses that both the Ensembl and UCSC

browsers are provided in web format as disclosed above (see cited material with

respect to claim 1).

Claims 1-5, and 7-20 are rejected under 35 U.S.C. 102(e) as being anticipated by

Sears et al. (Patent Publication #2003/0220820) with a priority date of November 13th,

2001.

Claim 1 is drawn to an interactive display system comprising a database of

comparative genomic data and a viewer.

Sears et al. provide for an interactive display system with a graphical viewer and

database of comparative genomic data, "[t]he present invention can be used to provide

a graphical interface for the visualization and analysis of genome informatics; . . .

display comparative genomic information from two or more organisms simultaneously . . . [and] allow a user to interact and manipulate the data through the display, " (paragraph 11, lines 1-9).

With respect to claim 2 with the additional limitation of an ortholog identifier, Sears et al. disclose the use of the BLAST program which is well known to those in the art as a means of finding orthology, " [t]he graphical interface can provide Basic Local Alignment Search Tool (BLAST) functionality," (paragraph 51, lines 1-2).

With respect to claim 3 with the additional limitation of the presence of syntenic anchors in the comparative genomic data, Sears et al. disclose, " [the] first type of biological data comprises at least one of . . . orthologous (syntenic) regions between mouse and human chromosomes, " (claim 9, lines 1-2 and 5).

With respect to claim 4 with the additional limitation of the two species being mouse and human, Sears et al. disclose the use of mouse and human sequences as disclosed above.

With respect to claim 5 with the additional limitation of comparative genomic data from at least three species, Sears et al.'s disclosure of a system that can display data from two or more species, can inherently display data from three or more species.

With respect to claim 7 with the additional limitation that the viewer contain a map viewer which shows genomic sequence information of the two or more species which markers, Sears et al. disclose the visualization of genomic sequence data from multiple species in the form of an ideogram and disclose the placement of markers for multiple species on these representations of genomic sequence data, "[t]he ideogram illustrates

the genes (or other markers) which have homology in other genome(s). Once a marker

is selected, homologous markers on the other genome(s) become visible," (paragraph

46, lines 8-11).

With respect to claim 8 with the additional limitation of a viewer that shows

contigs and fragments used to generate the contig, Sears et al. disclose that they

provide a method for, "displaying a first type of biological data and a second type of

biological data," (claim 1) wherein, " said first type of biological data comprises . . .

contigs of clones . . . CpG islands . . . [and] Simple Tandem Repeats, " (claim 9). Sears

et al. thus disclose a method of viewing contigs. Furthermore, since CpG islands and

Simple Tandem Repeats represent pieces of the genomic DNA and, since the contigs

are generated from those pieces of DNA, these elements of the genome represent

fragments used to generate the contig. Therefore, the ability to view these along with

the contigs provides for the system disclosed in claim 8 of the instant application.

With respect claim 9 with the additional limitation of a viewer that provides

annotation information associated with transcribed regions and to breadth of the claim in

the use of the phrase, "annotation information associated with transcribed regions,"

Sears et al. disclose several items viewable through their display system. Some of such

items viewable by the system of Sears et al. include, "gene boundaries, . . . gene

predictions from Project Ensembl, . . . Expressed Sequence Tags, Unigene data, . . .

Genscan data, predicted exons, [and] known genes, " (claim 9).

With respect to claim 10 with the additional limitation of a synteny viewer, Sears et al. disclose that their display system allows for the viewing of, "orthologous (syntenic) regions between mouse and human, " (claim 9).

With respect to claim 11 with the additional limitation of a multiple sequence alignment viewer, as cited above, Sears et al. disclose the ability to run BLAST searches from their display system. As the output of a BLAST search includes a multiple sequence alignment, in allowing the user to view the output of a BLAST search, the system is allowing for a mechanism by which one can visualize a multiple sequence alignment.

With respect to claim 12 with the additional limitation of a viewer that is able to show single nucleotides, Sears et al. disclose that the biological data able to be displayed by their system includes Single Nucleotide Polymorphisms (claim 9). Furthermore, Sears et al. disclose that, "individual gene data, ESTs, and SNPs link to related sequences," (paragraph 30). Thus by linking from a single nucleotide polymorphism, one can obtain single nucleotides.

Claims 13 and 15-18 are further limiting based upon the number of different viewers the system has (from two or more viewers to all six) from those disclosed in claims 7-12. Since the system disclosed by Sears et al. discloses all six viewers Sears et al. disclose the limitations of claims 13 and 15-18.

With respect to claim 14 with the additional limitation that the display system allow the user to select viewer components, Sears et al. disclose that, "data from a number of different objects are transparently organized and presented to a user. A user

can interact with any of the objects presented in the graphical interface and can explore

selected objects, " (paragraph 42). Since each of the viewer components are

transparent and only activated in response to an action by the user, the user has the

capability to select which viewer component they are interacting with at any given time

based upon the object they select. Furthermore, the user can enable or disable certain

viewer components based upon the level of detail at which they are viewing items in the

display.

Claim 19 is drawn to the additional limitation of the inclusion of a database with

"substantially complete genomic sequence."

In the absence of an explicit definition for the term, and given that Sears et al.

disclose the use of their methodology for, "genome informatics," (paragraph 11) and

disclose that their database, "includes genomic data," (claim 22), Sears et al. disclose a

database with a substantially complete genomic sequence.

Claim 20 is drawn to the additional limitation that the system is provided in a

stand-alone format. In the absence of an explicit definition for the term "stand-alone

format" and given that Sears et al. disclose a single computer system which constitutes

all of the necessary parts (claim 22), Sears et al. disclose a system in a stand-alone

format.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal   RA